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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David J. Vachon

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26813

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02/15/2011

MUETING, RAASCH & GEBHARDT, P.A.

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EXAMINER

HOLT, ANDRIAE M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,117	<b>Applicant(s)</b> VACHON ET AL.	
	<b>Examiner</b> Andriae M. Holt	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-17,30-32 and 34-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-17,30-32 and 34-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Andriae M. Holt.

Claims 15-17, 30-32, and 34-48 are pending in the application. Claims 15-17, 30, 35, 38, and 39 were amended and claims 40-48 were newly added in the submission on February 25, 2009. Claims 15-17, 30-32, and 34-48 will presently be examined to the extent they read on the elected subject matter of record.

### ***Information Disclosure Statement***

Receipt of Information Disclosure Statement filed October 5, 2009 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16, 38, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by the Anders (CA 2,259,097).

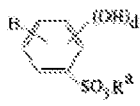
Anders discloses a hemo-compatible and bacterio-repellant hydrophilic, water-swallowable copolymer having repeating units of (A) at least one monomer that contains sulfate and/or sulfonate group, (B) at least one monomer that contains a carboxyl and/or

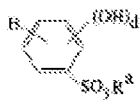
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carboxylate group and (C) at least one cross-linking agent that is at least bifunctional (polysulfonated block copolymer hydrogel) (page 1, lines 25-28). Anders discloses the copolymers may often absorb up to 100 times their own weight of water. Anders further discloses the copolymers are extremely hemocompatible, and greatly extend blood-coagulation times. This effect is as long-lasting as the powerful bacterio-repellant effect (page 2, lines 9-14). Anders discloses the combination of advantageous characteristics displayed by the copolymers is associated with good dermal and tissue compatibility, so that the copolymers are particularly suitable for medical applications (page 2, lines 17-22). Anders discloses the repeating units of the copolymers may originate directly from the cited monomers (A) and (B) (not chemically crosslinked) and from the cross-linking agent (C). Alternately, derivatives of these substances can be used, and they may be converted into the cited repeating units after polymerization. Anders discloses as an example, a sulphonic acid and/or carboxyl group may be converted into a sulfonate and/or carboxylate group subsequently (page 2, lines 24-27-page 3, lines 1-4) (convert acid form to the salt form). Anders discloses that the monomers (A) have a sulfate or sulfonate group that is important for the hemocompatibility and bacterio-repellant properties of the copolymers. Anders discloses that they can be polymerized radically, containing one or optionally two ethylene double bonds and one or optionally two sulfate and/or sulfonate groups with one equivalent of a physiologically acceptable cation, such as an alkali metal ion, in particular a sodium ion, as a counter ion (page 3, lines 17-26). Anders discloses suitable monomers (A) are described by the following general formula I: Formula I  $(C_nH_{2n-q-x})(SO_3R^a)_x$ , wherein n stand for an integer from 2 to 6; x stands for

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1 or 2, q stands for 0 or 2) and  $R^a$  stands for one equivalent of a cation, such as a metal ion, in particular an alkali metal salt (page 4, lines 4-15). Anders discloses that monomers (A) and (B) derived from benzene on page 4, lines 25-27-page 5 lines 1-11. Anders discloses that when  $R_c$  is a salt of  $-SO_3H$  and c is 1, then the Formula III is



represented by , preferably d is 0, and y is 0 (page 5, lines 17-20). Anders discloses examples of suitable monomers (A) are sodium 2-, 3-, or 4-vinylbenzenesulfonate (i.e., 2-, 3-, or 4-styrene sulfonate) (page 6, lines 7-10). Anders discloses that one monomer (A+B) that contains both the sulfonate and carboxylate groups is carboxylvinylbenzenesulfonate or a salt thereof, such as disodium 3-carboxylate-4-vinylbenzenesulfonate (page 6, lines 19-22) (salt of a polysulfonated block copolymer hydrogel).

Anders discloses that in a remarkable way, the coated surfaces exhibit both bacterio-repellant and cellular proliferating properties when the molar ratio is 2 to 10 (page 7, lines 8-9) (surfaces). Anders discloses that the cross-linking agents (C) are preferably radically polymerizable compounds containing two to four olefin double bonds. Cross-linking agents with two olefin double bonds form two-dimensional networks, whereas higher-functional cross-linking agents result in three-dimensional networks that do not swell as much, and form hydrogels with less water (page 7, lines 19-25). Anders discloses copolymers can be used for producing products in which hemocompatibility and/or bacterio-repellant properties are important. Anders discloses that the copolymer is suitable for producing articles such as compresses and wound

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dressings (wound dressing). It absorbs the watery liquid that escapes from wound, and has a simultaneous disinfecting action. Anders further discloses another use is as substrate for implant active substances. In addition, the hydrogel of the copolymer can serve as a water reservoir for plants and cut flowers; when used for this purpose, because of its bacterio-repellant properties, it also prolongs the life of cut flowers. Anders discloses that it can also be used for feminine hygiene products such as sanitary napkins and tampons (page 11, lines 8-21).

Anders meets all the limitations of the claims and thereby anticipates the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17, 34, 38-43, 45-46 and 48 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Anders (CA 2,259,097) in view of Cohen et al. (US 2,676,896).

### **Applicant's Invention**

Applicant claims a method for controlling biological organisms on a porous surface. Applicant claims the method comprising forming a water-insoluble coating comprising at least one salt of a polysulfonated block copolymer hydrogel on the porous surface in an article selected from the group consisting of a garment, a gas filter, a laboratory work surface, a laboratory wipe, and a wound dressing. Applicant claims the salt of the polysulfonated block copolymer hydrogel is an ammonium salt. Applicant claims the wound dressing comprises a substrate selected from the group consisting of a foam, a woven fabric, a knit fabric, and a nonwoven fabric.

### **Determination of the scope of the content of the prior art (MPEP 2141.01)**

The teachings of Anders with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

### ***Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)***

Anders does not specifically disclose that the salt of the polysulfonated block copolymer hydrogel is an ammonium salt or the wound dressing comprises a substrate selected from the group consisting of a foam, a woven fabric, a knit fabric, and a nonwoven fabric. It is for this reason Cohen et al. is joined as a secondary reference.

Cohen teaches that by applying a water-insoluble amine salt of sulfonated polystyrene to a textile that the objective of producing a material which has a soft, anti-static finish, which is characterized by good resistance to washing or laundering or dry

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cleaning, is met. Cohen teaches that such salt is applied to the textile material in various ways such as by treating the textile material with an aqueous solution of sulfonated polystyrene or a water-soluble salt of sulfonated polystyrene, such as a sodium salt. Cohen teaches that after treating the material with a liquid amine or with a water-soluble salt of an amine, which is capable of reacting with the sulfonated polystyrene or water-soluble salt of the sulfonated polystyrene to form a water-insoluble amine salt of sulfonated polystyrene (col. 1, lines 27-41). Cohen teaches the water-insoluble amine salts of sulfonated polystyrene may be applied to the textile material by coating one or more sides of the textile material with the water-insoluble amine salt of sulfonated polystyrene (col. 1, lines 25-34). Cohen et al. teach the term "textile material" is intended to include unspun fibers, both natural and synthetic staple fibers, yarns, or continuous filaments and woven and knitted fabrics (col. 2, lines 35-38). Cohen et al. teach the invention is particularly directed to the treatment of woven and knitted fabrics comprising a major portion of yarns of textile materials which readily acquire a static charge and which do not have good draping qualities when such static charge is present, especially in the case of apparel fabrics (col. 2, lines 51-55-col. 3, lines 1-2). Apparel fabrics are garments.

***Finding of prima facie obviousness  
Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Anders and Cohen et al. and use an ammonium salt of the polysulfonated block copolymer. Anders teaches that the monomers (A) have a sulfate or sulfonate group that is important for the hemocompatibility and bacterio-



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repellant properties of the copolymers. Anders further teaches they can be polymerized radically, and contain one or optionally two ethylene double bonds and one or optionally two sulfate and/or sulfonate groups with one equivalent of a physiologically acceptable cation, such as an alkali metal ion, as a counter ion. One skilled in the art at the time the invention was made would have been motivated to use an ammonium salt of the polysulfonated block copolymer because Cohen et al. teach that textiles that are coated with a water-insoluble amine salt of sulfonated polystyrene that are durable. In addition, Cohen et al. teach that by treating a water-soluble salt of sulfonated polystyrene, such as a sodium salt, the water-insoluble amine salts can be formed. As such, it would have been obvious to the skilled artisan to try an amine salt of a sulfonated polystyrene or convert a water-soluble salt of a sulfonated polystyrene to an amine salt of a sulfonated polystyrene in the formulations taught by Anders to produce more durable surfaces and wound dressings.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Anders and Cohen et al. and use a substrate selected from the group consisting of a foam, a woven fabric, a knit fabric, and a nonwoven fabric as the wound dressing. Anders teaches that the copolymer is suitable for producing articles such as compresses and wound dressings. It absorbs the watery liquid that escapes from wound, and has a simultaneous disinfecting action. One skilled in the art at the time the invention was made would have been motivated to use a foam, woven fabric, knit fabric, or a nonwoven fabric as the wound dressing because it is known in the art that these claimed substrates are used as wound dressings. The skilled

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artisan would have been further motivated to use the copolymers as disclosed by Anders because Cohen et al. teach that water-insoluble amine salts of sulfonated polystyrenes is added to textiles, woven fabric, knit fabric, and nonwoven fabric to produce textile finishing agents which provide a durable, anti-static finish on textile materials.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Claims 15-16, 30, 35-39, and 48 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Anders (CA 2,259,097) in view of Berlowitz-Tarrant et al. (US 5,840,387).

### ***Applicant's Invention***

Applicant claims a method for controlling biological organisms on a porous surface. Applicant claims the method comprising forming a water-insoluble coating comprising at least one salt of a polysulfonated block copolymer hydrogel on the porous surface in an article selected from the group consisting of a garment, a gas filter, a laboratory work surface, a laboratory wipe, and a wound dressing. Applicant claims the polysulfonated block copolymer hydrogel is a sulfonated styrene-ethylene-butylene-styrene triblock copolymer.

**Determination of the scope of the content of the prior art  
(MPEP 2141.01)**

The teachings of Anders with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

***Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)***

Anders does not specifically disclose the polysulfonated block copolymer hydrogel is a sulfonated styrene-ethylene-butylene-styrene triblock copolymer. It is for this reason Berlowitz-Tarrant et al. is joined as a secondary reference.

Berlowitz-Tarrant et al. teach that sulfonated multiblock copolymers are useful for providing non-thrombogenic coatings (Abstract). Berlowitz-Tarrant et al. teach that the multiblock copolymer is a sulfonated styrene-ethylene/butylene-styrene triblock copolymer (col. 1, lines 54-56). Berlowitz-Tarrant et al. teach that the term “block copolymer” is known in the art, and refers to a copolymer of two or more monomers in which the polymeric chains contain long stretches of one kind of repeating unit linked covalently to one or more long stretches of repeating units of one or more different polymers. Berlowitz-Tarrant et al. teach that preferred blocks include styrene, ethylene/butylene, isoprene, butadiene, propylene and the like (col. 2, lines 44-66). Berlowitz-Tarrant et al. teach the copolymers can be used as a coating to cover a substrate. Berlowitz-Tarrant et al. teach that exemplary substrates include metals, ceramics and polymers (natural or synthetic). Berlowitz-Tarrant et al. teach that the sulfonated styrene-ethylene/butylene-styrene copolymer can be effectively grafted to a variety of ceramic and polymer substrates (col. 3, lines 44-49).

***Finding of prima facie obviousness  
Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Anders and Berlowitz-Tarrant et al. and use sulfonated styrene-ethylene-butylene-styrene triblock copolymer as the polysulfonated block copolymer hydrogel. Anders teaches a hemo-compatible and bacterio-repellant hydrophilic, water-swellaable copolymer having repeating units of (A) at least one monomer that contains sulfate and/or sulfonate group, (B) at least one monomer that contains a carboxyl and/or carboxylate group and (C) at least one cross-linking agent that is at least bifunctional. Anders further teaches that the (A) monomer can be polymerized radically, containing one or optionally two ethylene double bonds and one or optionally two sulfate and/or sulfonate groups with one equivalent of a physiologically acceptable cation, such as an alkali metal ion. One skilled in the art at the time the invention was made would have been motivated to try sulfonated styrene-ethylene-butylene-styrene triblock copolymers taught by Berlowitz-Tarrant et al. in the copolymer hydrogels disclosed by Anders because based on the description of the copolymers described by Anders, monomer (A) reads on a sulfonated styrene-ethylene-butylene-styrene triblock copolymer. In addition, the skilled artisan would have been motivated to try a sulfonated styrene-ethylene-butylene-styrene triblock copolymers as the copolymer in the formulations taught by Anders because the copolymers of each reference have the same properties, water-insoluble and non-thrombogenic, which means they are hemocompatible and would provide the bacterio-repellant property to the substrate. Therefore, the skilled artisan would have been motivated to try sulfonated styrene-

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ethylene-butylene-styrene triblock copolymers with a reasonable expectation of success.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Claims 15-16, 31-32, 40, and 44-47 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Anders (CA 2,259,097) in view of Shalaby (US 6,413,539).

### **Applicant's Invention**

Applicant claims a method for controlling biological organisms on a porous surface. Applicant claims the method comprising forming a water-insoluble coating comprising at least one salt of a polysulfonated block copolymer hydrogel on the porous surface in an article selected from the group consisting of a garment, a gas filter, a laboratory work surface, a laboratory wipe, and a wound dressing. Applicant claims the coating additionally comprises a tetracycline. Applicant claims the tetracycline is doxycycline.

### **Determination of the scope of the content of the prior art (MPEP 2141.01)**

The teachings of Anders with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

### **Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)**

Anders does not specifically disclose the coating additionally comprises tetracycline, wherein the tetracycline is doxycycline. It is for this reason Shalaby is joined as a secondary reference.

Shalaby teaches a hydrogel-forming, self-solvating, absorbable polyester copolymer capable of selective, segmental association into a compliant hydrogel mass on contact with an aqueous environment (col. 6, lines 33-37). Shalaby teaches the copolymer comprises a base component, designated "Component A". Shalaby teaches Component A comprises a molecular chain having a hydrophilic block (col. 7, lines 1-25). Shalaby teaches these copolymers are especially useful for localized controlled delivery of biologically active agents/drugs and protecting or augmenting damaged, compromised, and/or traumatized tissues. Shalaby teaches the applications of the novel copolymers include treatment of periodontal disease, wherein a tetracycline-doxycycline- or chlorhexidine-containing hydrogel-former is injected into the periodontal pocket to form an adhesive gel or semi-solid mass in the pocket for the controlled release of such antimicrobial drugs over a period of 2 to 45 days (col. 9, lines 65-67-col. 10, lines 1-7).

***Finding of prima facie obviousness  
Rationale and Motivation (MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Anders and Shalaby and additionally use tetracycline in the coating and wherein the tetracycline is doxycycline. Anders teaches the copolymers can be used for producing products in which hemocompatibility and/or bacterio-repellant properties are important. Anders further teaches that the copolymer is

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suitable for producing articles such as compresses and wound dressings. It absorbs the watery liquid that escapes from wound, and has a simultaneous disinfecting action.

Anders further discloses another use is as substrate for implant active substances. One skilled in the art at the time the invention was made would have been motivated to use an additional active such as tetracycline because Anders specifically teaches that the copolymers are used as a substrate for active substances. The skilled artisan would have been motivated to use a tetracycline such as doxycycline because Shalaby teaches that a tetracycline, doxycycline is used as an active antimicrobial component on hydrogels. Therefore, it would have been obvious to the skilled artisan to combine two antimicrobial agents, the polysulfonated copolymer and doxycycline to improve the antimicrobial activity of the copolymer hydrogel. Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two or three conventional antimicrobial, anti-bacterial agents set forth *prima facie* obvious subject matter. Therefore, one skilled in the art at the time of invention would have been motivated to combine antimicrobial agents to increase the efficacy of the agents to effectively control bacteria.

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Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt,  
Patent Examiner  
Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616